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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,043	11/17/2003	Richard M. Chesbrough	71202-45	4168
69683	7590	01/25/2008	EXAMINER	
ENRIQUE ABARCA 5914 WEST COURTYARD DRIVE SUITE 200 AUSTIN, TX 78730			WEATHERBY, ELLSWORTH	
		ART UNIT	PAPER NUMBER	
		3768		
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		01/25/2008	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/707,043	CHESBROUGH ET AL.
	Examiner Ellsworth Weatherby	Art Unit 3768

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 30 October 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-75 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-75 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>3/07/2007</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group 1 (claims 1-75) in the reply filed on 10/30/2007 is acknowledged. The traversal is on the ground(s) that examination is not believed to create and undue burden. This is not found persuasive because the two inventions, Group 1 (claims 1-75) and Group 2 (Claims 76-82) have materially different functions and do not require the particulars of each other.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-13, 36, 60, and 68-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Foerster et al. (Pub. No. 2001/0034528).

4. Foerster et al. teaches an apparatus which is capable of delivering a marker to a tissue mass, comprising: A trackable cannula defining a lumen and having a distal end forming an insertion tip [0002; 0047; 0054] and a localization wire [0011-0012; 0018-0019] located within the lumen and having a distal end near the insertion tip when the cannula is in the insertion position and an actuator in operable communication with the cannula and operable between a charged condition and a discharged condition to effect

the relative movement of the cannula and the localization wire to expose the distal end of the localization wire to the tissue mass [0019]; wherein, to implant the localization wire into the tissue mass, the cannula is inserted into the tissue mass and the actuator is placed in the discharged condition to effect relative movement of the cannula and the localization wire and expose the distal end of the localization wire to the tissue mass [0018; 0054]. Foerster et al. also teaches using a sharpened insertion tip to aid in the insertion of the cannula into the tissue mass [0019]. Foerster et al. also teaches that the localization wire comprises at least one anchor for holding the localization wire in the tissue mass and that the anchor extends beyond the distal end of the cannula when the actuator effects the relative movement of the cannula and the localization wire [0019]. Foerster et al. also teaches other embodiments where the marker element has blunt, rather than sharpened edges, but is adapted to expand sufficiently (or change countour) upon exiting from the tube that its edges press radially against the selected tissue, thereby wedging and implanting the marker element or providing integrally formed barbs to aid in the positioning of the marker coil [0019; 0059].

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 14-17, 37-39, and 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. in view of St. Germain et al. (USPN 5,534,007).

7. Foerster et al. teaches all the limitations of the claimed invention except for expressly teaching that the actuator retracts the cannula relative to the localization wire from an insertion position to an implant position to effect the relative movement of the cannula and localization wire and expose the distal end of the localization wire. Foerster et al. also does not expressly teach that the actuator comprises a slide that is manually moved by the user from the charged to the discharged condition to retract the cannula relative to the localization wire. Foerster et al. also does not expressly teach the actuator comprises a slide that is automatically moved from the charged to the discharged condition to retract the cannula relative to the localization wire.

8. St. Germain et al. teaches manually retracting the outer face of a longitudinal insertion shaft to expose a device, where the device is contained within the shaft before the shaft is retracted and upon retracting the shaft the device becomes deployed (Abstract; col. 3, l. 60- col.4, l. 52). St. Germain et al. does not expressly teach that the sliding shaft is automatically retracted. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to convert a manual sliding of the shaft to an automatic sliding of the shaft for the purpose of improving reproducibility or to allow the operator to focus on positioning instead of retraction.

9. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Foerster et al. in view of St. Germain et al. The motivation to modify Foerster et al. in view of St. Germain et al. would have been to use a well known

method of positioning an internal device that involves using the tip of the shaft to position the localization wire at or in the target, as taught by St Germain et al.

10. Claims 18-19, 40-41, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. in view of St. Germain et al. as applied to claims 17, 39, and 64 above, and further in view of Burbank et al. (USPN 6,716,179).

11. Foerster et al. in view of St. Germain et al. teaches all the limitations of the claimed invention except for expressly teaching that the actuator comprises a trigger operable between a ready position and a release position for controlling the operation of the biasing element.

12. In the same field of endeavor, Burbank et al. teaches a trigger operable between a ready position and a release position for controlling the operation of an actuator to controllably release an implant from a compressed state to an expanded state from within a slidable sheath (col. 11, ll. 25-40).

13. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Foerster et al. in view of St. Germain et al. with Burbank et al. . The motivation to modify Foerster et al. in view of St. Germain et al. with Burbank would have been to provide controllable insertion using a simple, repeatable device.

14. Claims 20-30, 42-55, and 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. in view of St. Germain et al. and Burbank et al. as

applied to claims 19, 41, and 65 above, and further in view of Truckai et al. (USPN 6,813,520).

15. Foerster et al. in view of St. Germain et al. and Burbank et al. teaches all the limitations of the claimed invention except for expressly teaching a handle defining a hollow interior and an end, with the cannula being slidably mounted to the end wherein the handle comprises a base and a grip, with the grip being slidably mounted to the base for movement between a first position, where the cannula and localization wire are substantially received within the grip, and a second position, where the cannula and localization wire are substantially exteriorly of the grip. Foerster et al. in view of St. Germain et al. and Burbank et al. also do not expressly teach that the spring is disposed between the base and the grip and the spring is compressed when the grip is moved to the second position or that it is disposed between the base and the grip and the spring is compressed when the grip is moved to the second position. Foerster et al. in view of St. Germain et al. and Burbank et al. also do not expressly teach having proximal end that is mounted to a base. Foerster et al. in view of St. Germain et al. and Burbank et al. also do not expressly teach that the trigger is pivotally mounted to the handle and includes a finger (or key) that abuts the collar (or keyway) when the trigger is in the ready position, and can be pivoted to the release position to remove the finger from abutting contact with the collar to release the spring.

16. Truckai et al. teaches a handle defining a hollow interior and an end, with the cannula being slidably mounted to the end wherein the handle comprises a base and a grip, with the grip being slidably mounted to the base for movement between a first

position, where the cannula and an internal device are substantially received within the grip, and a second position, where the cannula and localization wire are substantially exteriorly of the grip (col. 7, l. 52- col. 8, l. 7). Truckai et al. also teaches providing a spring that is disposed between the base and the grip and the spring is compressed when the grip is moved to the second position or that it is disposed between the base and the grip and the spring is compressed when the grip is moved to the second position (col. 8, ll. 8-28). Truckai et al. further teaches a locking mechanism that may be provided to hold the shaft in the fully withdrawn condition to prevent inadvertent closure of the spring members during the procedure (col. 8, ll. 28-32).

17. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Foerster et al. in view of St. Germain et al. and Burbank et al. in view of Truckai et al. The motivation to modify Foerster et al. in view of St. Germain et al. and Burbank et al. in view of Truckai et al. would have been to use a well known method that allows simple manipulation of a device's distal tip by the user operating the device from the proximal end, as taught by Truckai et al.

18. Claims 31-35, 56-59, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. in view of Truckai et al.

19. Foerster et al. teaches all the limitations of the claimed invention including where upon movement of the sheath an actuator is moved to a charged condition [0019]. However, Foerster et al. does not expressly teach a handle having a base mounting a proximal end of the cannula, and a grip slidably mounted to the base for movement

between a first position, where the cannula is substantially received within the grip, and a second position, where the cannula is substantially exteriorly of the grip.

20. Truckai et al. teaches a handle defining a hollow interior and an end, with the cannula being slidably mounted to the end wherein the handle comprises a base and a grip, with the grip being slidably mounted to the base for movement between a first position, where the cannula and an internal device are substantially received within the grip, and a second position, where the cannula and localization wire are substantially exteriorly of the grip (col. 7, l. 52- col. 8, l. 7). Truckai et al. also teaches providing a spring that is disposed between the base and the grip and the spring is compressed when the grip is moved to the second position or that it is disposed between the base and the grip and the spring is compressed when the grip is moved to the second position, thus automatically effecting the relative movement between the cannula and the internal device (col. 8, ll. 8-28). Truckai et al. further teaches a locking mechanism that may be provided to hold the shaft in the fully withdrawn condition to prevent inadvertent closure of the spring members during the procedure (col. 8, ll. 28-32).

21. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Foerster et al. in view of Truckai et al. The motivation to modify Foerster et al. in view of Truckai et al. would have been to use a well known method that allows simple manipulation of a device's distal tip by the user operating the device from the proximal end, as taught by Truckai et al.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ellsworth Weatherby whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EW

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